REMARKS

Claims 1-26 are currently pending. Applicant respectfully requests that the above application be reconsidered, as amended. Applicant asserts that the claims as amended are fully supported in the application as originally filed and contain no new matter, and respectfully request reconsideration for the following reasons.

I. Claim Rejections under 35 USC §102(b) – rejection of Claims 1, 3-11, 15, and 17

Claims 1, 3-11, 15, and 17 have been rejected under 35 USC §102(b) as anticipated by Beck, Jr. et al., US Patent No. 5,339,809 ("Beck"). Regarding Claim 1, Beck allegedly discloses a cricothyroidal endotracheal device for insertion between the cricoid and thyroid cartilages for treatment of chronic respiratory disorders that comprises a short distal section of tubing; an intermediate section of tubing; a pre-formed obtuse angle bend in the tube between the distal and intermediate sections; an elongated proximal section of tubing; a pre-formed abrupt bend in the tube between the intermediate and proximal sections; and an inflatable cuff 16 integrated into the distal section of tubing. Applicant respectfully traverses this rejection.

To anticipate a claim, the reference must disclose each limitation of the claim at issue. Contrary to the Examiner's assertion, Beck does not disclose all of the limitations of claim 1. First, the end tube section 2 disclosed by Beck is not short, but rather elongated. Second, proximal tube section 12 disclosed by Beck is not elongated, but short. Both of these differences are limitations recited in Claim 1, as well as in Claims 3-11, 15, and 17, of the present invention that are not disclosed by Beck. As such, Beck does not disclose each limitation of Claims 1, 3-11, 15, and 17.

i) The Distal Tube Section Disclosed by Beck is Not Short:

As shown in FIG. 2 of Beck, the distal tube section of Beck comprises an end tube section 2 having holes 6 therealong. This end tube section 2 is joined at its proximal end to the distal end of tube section 8 (the intermediate section of the tube). An angle of 90° to 130° is then provided between the ends of tube section 8. In FIG. 2, tube section 8 is configured with accordion pleats 10, and its proximal end is connected to the distal section of proximal tube

section 12. Tube section 12 is then connected to an oxygen air source 13, and FIG. 2 depicts tube section 12 with and abrupt bend, although this feature is not further disclosed in the patent.

Rather than categorizing end tube section 2 as being short, the end tube section 2 of FIG. 2 is categorized by Beck as being elongated. Claim 1 of Beck recites "a first elongated and hollow tube portion..." (Emphasis added), which corresponds to end tube section 2 of FIG. 2 before it reaches the angle of 90° to 130° within tube section 8. In light of Claim 1 of Beck and the visual depiction of an elongated tube section 2 in FIG. 2, it is simply incorrect to characterize Beck's end tube section 2 as "short," when it is readily apparent that this section of tubing is elongated, and even the longest section of the entire tube.

In contrast, the distal section of tubing of the present invention is properly categorized as a short section, which is illustrated in FIGS. 1 and 2 of the Applicant's published application, US 2004/0123869 ("the published application"). The length of the distal section of tubing 12 before is reaches abrupt bend 16 is obviously short when compared to the length of the proximal section of tubing 18 before it reaches bend 20. The same cannot be said for the Beck tube.

The evident difference between the elongated distal end of the Beck tube versus the short distal end of Applicant's tube can be further clarified by reviewing the differing insertion points of the two tubes within the trachea. As disclosed in the published application, the tube of the present invention must necessarily have a short distal section to avoid the placement of the end of the tube into a bronchus. The reason for this is that this tube is primarily used "for patients with a temporary or permanent tracheotomy." (See page 2, para. 28 of the published application). The typical insertion point for a standard tracheotomy is through an incision between the second and third tracheal rings, as seen best at p. 148, Figure 3-9 of the *Anesthesiologist's Manual of Surgical Procedures*, 1999 ("the *Anesthesiologist's Manual*"), attached hereto as Exhibit A.[1] As explained at page 2, paragraph 27 of the published application, the "short distal section of the tracheotomy endotracheal tube allows it to be placed in the trachea without risk of it lying in a bronchus, and without needing to trim the tube and its integrated cuff." Therefore, the tube of

[1] See also Beck, column 1, lines 18-20: "The typical insertion point for a standard tracheostomy is through the second, third or fourth ring of tracheal cartilage below the voice box."

the present invention must necessarily have a short distal section because of its low insertion point into the trachea and the resulting short distance to the bronchi.

In contrast, the tube disclosed by Beck was designed for "a modified cricothyrotomy procedure not normally used with chronic patients." (See Beck, column 1, lines 58-60). The insertion point for the Beck tube is much higher, "between the upper margin of the cricoid cartilage 32, FIG. 1, and the lower margin of the thyroid cartilage 30." (Beck, column 3, lines 8-10). This higher insertion point is best seen in p. 513, Figure 7.13-1 of the *Anesthesiologist's Manual*, attached hereto as Exhibit B. Indeed, a flange, and not the length of the distal end of the Beck tube, keeps it from entering the lungs. Looking at FIG. of Beck, "flange 14 on tube 12, which may be a disc on the exterior of tube 12 [...] prevents the tube from being inserted to deeply into the trachea. Thus, the end 4 of the tube is just above the bifurcation of the trachea into the right and left bronchi." (See col. 3, lines 18-23). Thus, Beck acknowledges that the tube has the potential to end up in a bronchus. If a tube having an elongated distal section, such as that of Beck, were to be placed at the insertion point contemplated by the present invention, it would sit in the right mainstem bronchus, and would either need to be trimmed or else partially removed. The present invention provides a short distal tube section to solve this very problem.

ii) **The proximal tube section 12 disclosed by Beck is not elongated:**

In addition to Beck not disclosing the limitation of a short distal tube section, the proximal section of tubing of Beck is not elongated as alleged by the Examiner, but rather is short, in contrast to the necessarily elongated proximal section of the tube of the present invention.

In claim 1, Beck refers to the intermediate tube section 8 of FIG. 2 as "a second hollow and elongated tube portion...", and, refers to proximal tube section 12: "a third hollow tube portion...". The fact that the intermediate section 8 is characterized by Beck as "elongated" (as is the end tube section 2, noted above), yet the proximal tube section 12 is not so characterized, leads to the conclusion that the proximal tube section 12 of Beck is a relatively short section of the tube as compared to the elongated distal and intermediate sections. Indeed, upon inspection of both FIG. 2 of Beck, it is readily apparent that Beck's proximal tube section 12 is shorter than, and the shortest of, the other sections of the tube. In contrast, the proximal section of tubing

disclosed in the present invention is necessarily an elongated section, which is apparent in FIGS. 1 and 2 of the published application.

As explained at page 2, paragraph 27 of the published application, the "long proximal section of the tube allows an anesthesiologist to readily connect it to anesthetic tubing at a distance away from the patient's body." Thus, the elongated proximal section of the tube of the present invention is intentionally made long to solve a problem that anesthesiologists commonly have, namely access to the endotracheal tube beneath the drapes during surgery. Beck neither acknowledges nor solves this problem. Rather, Beck is more concerned with the diameter of its tube, not its proximal length: "Unlike tracheostomy and emergency cricothyrotomy where relative large diameter tubes...are employed, in the instant invention a relatively small diameter tube...is connected...to an oxygen...air source." (Beck, columns 1, line 60 to column 2, line 7) (Emphasis added). Nowhere does Beck address the need to have an elongated proximal section of tubing in his invention, and indeed there is no elongated proximal section of tubing disclosed by Beck.

For the above reasons, it is simply incorrect to state that the distal tube section of Beck is "short" like that of the present invention, and that the proximal tube section of Beck is "elongated" like that of the present invention. Beck does not disclose such a tube, and so does not anticipate Claim 1 of the present invention. For the same reasons, independent Claim 17, which includes the above elements of Claim 1, is not anticipated by Beck. Applicant also submits that Claims 3-11, 15, since they are dependent on Claim 1, are likewise not anticipated. Applicant therefore respectfully requests the rejection be withdrawn and Claims 1, 3-11, 15, and 17 be duly allowed.

II. Claim Rejections under 35 USC §103(a) – rejection of Claims 2, 12, 18-20, 23-25

Claims 2, 12, 18, 19, 20, 23, 24, and 25 stand rejected under 35 USC §103(a) as allegedly being unpatentable over Beck, Jr. et al., US Patent No. 5,339,809 ("Beck") in view of Nye, US Patent No. 5,590,647 ("Nye"). Examiner alleges that Beck discloses the invention with the exception of providing a flexible tube that is made of a thermoplastic material preformed to the shape desired, and that Nye discloses a method of providing anesthesia with a specialized

tracheal tube that does provide a flexible material that is made of a thermoplastic material preformed to the shape described.

Applicant asserts that the rejected claims, as amended, are unobvious. To articulate a *prima facie* case of obviousness, the art cited against the pending claims must teach all the limitations of the rejected claims. The prior art must also provide a motivation to combine those references to achieve the claimed invention, and provide to the skilled artisan a reasonable expectation of success in achieving the claimed invention. Claims 2, 12, 18 and 23 have been amended to recite: "wherein **all sections and bends of the flexible tube** are made of a thermoplastic material preformed to the shape described." (Emphasis added). In light of the claims as currently amended and the following remarks, Applicant contends that none of these criteria have been met by the above-cited references, neither individually or in combination.

Even if Beck is assumed to disclose the invention with the exception of providing a flexible tube that is made of a thermoplastic material preformed to the shape desired (an assumption that Applicant asserts is not correct, given the argument in Section I., above), Nye teaches away from a flexible tube that is entirely made of a thermoplastic material preformed to the shape described. Although Nye describes in detail the advantages of a specialized tracheal tube having a flexible portion which allows for movement of the proximal end relative to the distal end, thereby allowing access to the head and neck of a patient during surgery, it downplays and even lists as a disadvantage to have the entire endotracheal tube made of flexible material having a memory, i.e., having sufficient resiliency such that the tube will return to its pre-formed shape following flexure. For example, Nye notes that preformed tubes have disadvantages at column 2, line 61 – column 3, line 13:

> [T]he curve of the preformed tubes must be controlled accurately to correspond with the anatomy of the patient. While standard sizes and shapes will be appropriate for most patients, there are many occasions when the predetermined curve will leave the proximal extension at an improper distance from the facial region. This may result in excessive pressure being exerted on sensitive tissue in the nasal and oral regions, as well as to the mucosa and trachea at the distal end of the tracheal tube. [...] Also, the preformed tracheal tubes do not allow for shifting of the tube during an operation, but rather may be positioned in only one way.

The flexibility feature of the tube disclosed by Nye is thus not a result of the entire tube being flexible and in a preformed shape, as is the present invention, but rather a flexible portion that allows for movement of the proximal end relative to the distal end of the tracheal tube without creating stress at the proximal or distal ends. Claim 1 of Nye recites "a tracheal tube including a distal end portion for intubation into a patient; **a flexible intermediate portion** smoothly merged with said distal end portion; and a proximal end portion smoothly merged with said intermediate portion; [and] moving said proximal end portion via said flexible intermediate portion to a second position relative to the head and neck of the patient." (Emphasis added)

The term "flexible," as used by Nye, is a relative term. In one instance Nye refers to forming the distal and proximal end portions of the tube from a flexible material, e.g. "of a material having sufficient resilience to return to a preformed shape following flexure thereby enabling said distal end portion to conform to the posterior pharynx and trachea of said patient" (See Claim 5 of Nye). In another instance, Nye refers to the flexible intermediate portion of the tube being formed of "a material which allows for bending at acute angles without kinking or transferring unnecessary force to said proximal end portion or said distal end portion." (See Claim 8 of Nye). Thus, Nye discloses that the flexible intermediate portion of the tube is more flexible than the distal or proximal ends, in order to solve the perceived problems associated with having the entire tube made of a material having a memory that will return to its pre-formed shape following flexure.

In contrast to Nye, all of the sections and bends of the tube, i.e. the entire tube, of the present invention is made of a material having a memory that will return to its pre-formed shape following flexure, not just the proximal and distal ends. Claims 2, 12, 18 and 23 have been amended to better reflect this fact. Claims 19 and 20, which depend from claim 19, and Claims 24 and 25, which depend from Claim 23, also incorporate this amendment.

Rather than disclosing a limitation not disclosed by Beck, Nye teaches away from having the entire tube made of a thermoplastic material preformed to the shape desired. Therefore, since none of the cited references expressly or implicitly teach or suggest, individually or in combination, all of the limitations of the rejected claims, as amended, or provide any motivation for one of ordinary skill in the art to modify the references or to combine the referenced

teachings, the proposed combinations described above fail to articulate a *prima facie* case of obviousness. Applicant therefore respectfully requests the rejection be withdrawn and Claims 2, 12, 18, 19, 20, 23, 24, and 25, as amended, be duly allowed.

III. Claim Rejections Under 35 USC §103(a) – rejection of Claims 13, 14, 16, 21, and 22

Claims 13, 14, 16, 21, and 22 stand rejected under 35 USC §103(a) as being unpatentable over Beck, Jr. et al., US Patent No. 5,339,809 ("Beck") in view of Joseph, US Patent No. 5,582,167 ("Joseph"). Examiner alleges that Beck discloses the invention with the exception of providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate, and that Joseph teaches a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate. Applicant respectfully traverses this rejection.

Applicant asserts that the rejected claims are unobvious. To articulate a *prima facie* case of obviousness, the art cited against the pending claims must teach all the limitations of the rejected claims. The prior art must also provide a motivation to combine those references to achieve the claimed invention, and provide to the skilled artisan a reasonable expectation of success in achieving the claimed invention. In light of the following remarks, Applicant contends that none of these criteria have been met by the above-cited references, neither individually or in combination.

Even if Beck is assumed to discloses the invention with the exception of providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate (an assumption that Applicant asserts is not correct, given the argument in Section I., above), Joseph does not teach a tracheostomy tube that provides a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate. Indeed, Joseph does not disclose or even mention a tracheostomy tube at all. Joseph teaches an endotracheal tube (i.e. a tube inserted through the mouth or the nose) that provides a means to conveniently irrigate and drain the subglottic region below the vocal cords and above an inflated cuff (See Abstract of Joseph), and notes that "the apparatus disclosed herein is most preferably incorporated into endotracheal tubes." (See column 4, lines 47-48). Nowhere does Joseph teach or suggest use of the invention with a tracheotomy tube.

Furthermore, Joseph does not teach or suggest a supplemental eye or port with a tracheotomy, while the present invention discloses a tracheotomy tube having a supplemental eye or port opening 26 adjacent to the beveled terminal end 24 of distal section 12. This port 26 provides ventilation for the lungs as well as for the upper lobes should the tube be accidentally advanced onto the carina at the lower end of the trachea or into a main stem bronchus (See FIG. 1 of the published application). While it is true that FIG. 1 of Joseph depicts the endotracheal tube with what can be construed as an eye or port adjacent to a beveled terminal end, this port is neither labeled in FIG. 1 nor discussed in the specification, and is not part of the claimed invention of Joseph. Rather, Joseph is concerned more about disclosing an irrigation channel that delivers liquids such as saline or antibiotic and antifungal medications for mucosal hydration, and bactericidal action against infected subglottic secretions. An outer sleeve surrounding the endotracheal tube forms a suction lumen for removing the secretions. Electronic and mechanical controls provide regulated volume infusion and regulated suction. (See Abstract of Joseph).

Rather than disclosing a limitation not disclosed by Beck, Joseph does not even teach or suggest use of the invention with a tracheotomy tube; much less a tracheotomy tube that provides a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate. Although FIG. 1 of Joseph depicts what may be called an eye within the distal beveled end of the endotracheal tube, it is not labeled in FIG. 1, its presence is not addressed in the specification, and it is not claimed as part of the invention. Therefore, since none of the cited references expressly or implicitly teach or suggest, individually or in combination, all of the limitations of the rejected claims, as amended, or provide any motivation for one of ordinary skill in the art to modify the references or to combine the referenced teachings, the proposed combinations described above fail to articulate a *prima facie* case of obviousness. Applicant therefore respectfully requests the rejection be withdrawn and Claims 13, 14, 16, 21, and 22 be duly allowed.

IV. The Ratios Between the Sections of Tubing are Not a Simple Matter of Design Choice

With reference to Claims 23 and 26, the Examiner asserts that the ratio between the length of the Distal section to the length of the Intermediate section, and the ratio between the

length of the Proximal section to the length of the Distal section, are a simple matter of design choice. Applicant disagrees, and states that these ratios have a functional importance relating to the anatomy of the average patient, adult or child, male or female, requiring a tracheotomy.

In addition to the foregoing argument above in Section I., relating to the necessity for the Distal section of the tube of the present invention to be short, and the necessity for the Proximal section to be elongated, Claims 23 and 26 specify certain ratios of length between the length of the Distal section and the Intermediate section, and the Proximal section and the Distal section. The published application notes that the tracheotomy endotracheal tube of the invention is useful for individuals of all ages. (See page 2, para. 28 of the published application) "The length of the distal, intermediate, and proximal sections will vary depending on the size of the tracheotomy endotracheal tube, e.g., whether it is intended for use on an adult or a child." (Page 2, para. 34 of the published application). As is well known in the art, the pediatric and adult upper airway anatomies differ. For example, the pediatric head is large with a small face, mandible, and external nares, the neck is relatively short, and the tongue is large relative to the mouth. The narrowest part of the pre-pubertal upper airway is below the vocal cords at the cricoid ring, at the level of C3-C4, allowing the use of uncuffed endotracheal tubes in children (unlike in adults). The upper airway anatomy of both males and females differs slightly as well, when comparing males and females of the same age group, with females being on the average slightly smaller than males.

These differences in the actual size between the adult, pediatric, male and female airways can be significant. For example, the intermediate and distal sections of a tube made according to the present invention for a child will not fit the airway of an adult, and vice versa. However, the overall proportions in upper airway size between adult, pediatric, male and female airways is basically the same. Proportion refers to the relationship of the vertical to the horizontal dimension, as well as depth. Because average human beings fit within a predictable range of sizes and proportions, the tube of the present invention can be manufactured within the disclosed ratios in order to fit all sizes of individuals. That is, the ratios disclosed are the same for a tube manufactured for either an average adult or an average child, male or female, and allow one to

make the claimed tracheotomy tube for patients of all ages, regardless of the actual size of the patient.

More specifically, as disclosed, to manufacture the tube of the present invention for individuals of all ages (i.e. both children and adults, male or female), the ratio between length of the Distal section to the length of the Intermediate section is typically between about 1.0 to about 2.0, and more typically between about 1.2 to about 1.8, and the ratio between the length of the Proximal section to the length of the Distal section is typically between about 2.0 to about 4.0, and more typically between about 2.5 to about 3.5.

Further, the claimed bends 16, 20 in the tube of the present invention mark the transitions between the sections (Distal, Intermediate and Proximal) of tubing, and dictate the disclosed ratios. These bends 16, 20 correspond to specific parts of the human anatomy, with pre-formed bend 16 conforming to the bend created at the transition between the tracheotomy stoma and the trachea (see page 2, para. 30 of published application), and bend 20 conforming to the bend created at the transition between the stoma and the chest wall of a patient (see page 2, para. 31). Since the Intermediate section is needed to cover the distance between the trachea and the chest wall, which is a short distance in the average human, this section is the shortest section of tubing. The disclosed ratios reflect this fact. Further, the Distal section is also short, typically about the same length as, or slightly longer than, the intermediate section, since the Distal section of the tube must be shorter than the distance between the stoma and the bronchi to prevent endobronchial intubation. The disclosed ratios reflect this as well. The Proximal section of tubing is necessarily elongated in order to allow the anesthesiologist access to the tube and to keep the tube away from the body cavity of the patient during use (page 2, para. 32). For this reason, the Proximal section generally is at least twice as long as the Distal section, and typically is about three times as long as the Distal section (page 2, para. 34).

As can be seen from the preceding arguments, the tube of the present invention includes a Distal tube section that is necessarily short, a Proximal tube section that is necessarily elongated, and the bends between the various sections which conform to the human anatomy involved in a tracheostomy insertion. All of these elements have criticality in the design and function of the tube, so that it can be useful for individuals of all ages. The ratios disclosed in Claims 23 and 26

correspond to these functional features of the tube, and are not a result of simple design choice. Therefore, Applicant respectfully requests that this rejection be withdrawn and claims 23 and 26 be allowed.

CONCLUSION

Applicant believes that each point raised in the pending Office Action has been addressed. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the present rejections, and that a timely Notice of Allowance be issued in this case.

The Examiner, however, is invited to contact the undersigned directly with any questions or remaining issues regarding the pending claims.

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